

AB-311U

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REMARKS

This is a full and timely response to the non-final Official Action mailed June 22, 2006. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

By the forgoing amendment, various claims have been amended. Additionally, new claims 21-25 have been added. No claims have been cancelled. Thus, claims 1-25 are currently pending for further action.

Double Patenting:

The recent Office Action *provisionally* rejects claims 1-20 on the grounds of non-statutory obviousness-type double patenting in view of claims 1, 2, 4-9, 11 and 12-17 of co-pending Application No. 10/731,551 in combination with the teachings of U.S. Patent No. 5,824,021 to Rise ("Rise"). Because this is a provisional rejection, Applicant declines to take any position at this time on the question of whether claims 1-20, as they may evolve during prosecution of this application, relate to the claims of Application No. 10/731,551 in view of Rise. Should Application No. 10/731,551 issue prior to the present application, Applicant reserves the right to then revisit the relationship, if any, between the claims of the two applications and to file a terminal disclaimer as to Application No. 10/731,551 in this application, if needed.

AB-311U

10/730,689

Prior Art:

The recent Office Action rejected claims 1-20 as unpatentable under 35 U.S.C. § 103(a) over the combined teachings of U.S. Patent No. 6,058,331 to King ("King"); "Modification of Blood Flow to the Extremities by Electrical Stimulation of the Nervous System," by Dooley and Kasprak ("Dooley"); and U.S. Patent No. 5,193,540 to Schulman ("Schulman"). For at least the following reasons, this rejection is respectfully traversed.

Claim 1 recites:

A method for treating a patient with peripheral vascular disease (PVD) or angina, comprising:

- providing a miniature leadless implantable stimulator with at least one electrode and with a size and shape suitable for placement entirely within the spinal column;
- implanting the stimulator within said spinal column* and adjacent to at least one tissue influencing blood circulation, which tissue is at least one of the spinal roots;
- providing operating power to the stimulator;
- using an external appliance to transmit stimulation parameters to the stimulator;
- receiving the stimulation parameters at the stimulator;
- generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
- delivering stimulation pulses via the stimulator to the at least one of the spinal roots influencing blood circulation as a treatment for PVD or angina.

(Emphasis added).

The recent Office Action concedes that King and Dooley fail to teach or suggest the claimed stimulator that is "suitable for placement entirely within the spinal column." (Action of 6/22/06, p. 5). Consequently, the Action cites to Schulman. According to the Action, Schulman "discloses a miniature implantable stimulator (see figure 4). The stimulator is of such a size and shape (2mm x 10mm) that it is suitable for placement entirely within the spinal column of a patient using a hypodermic needle (Col. 3, lines 53-68)." (*Id.*).

AB-311U

10/730,689

This statement would suggest that Schulman teaches implanting a stimulator within a spinal column as claimed. This, however, is not actually the case. While it may be possible to implant the stimulator taught by Schulman within a patient's spinal column, MPEP 2143.01 makes clear that the mere "fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness." MPEP 2143.01 further states that the "fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness," but rather, "the prior art must suggest the desirability of the claimed invention."

Not only does Schulman not teach or suggest implanting a stimulator within a spinal column, claim 1 is a method claim and calls expressly for actually implanting a stimulator within a spinal column to treat PVD or angina. There is no teaching or suggestion in any of the prior art references of record of implanting a stimulator within a patient's spinal column to treat PVD or angina.

To the contrary, King teaches away from the claimed invention in this regard by expressly teaching that only a lead, not the implantable stimulator, is placed in the spinal column. (King, col. 5, lines 2-10). None of the applied references, Schulman included, teaches or suggests "implanting the stimulator within said spinal column and adjacent to at least one tissue influencing blood circulation, which tissue is at least one of the spinal roots" as a treatment for PVD or angina. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least these reasons, the rejection of claim 1 and its dependent claims should be reconsidered and withdrawn.

AB-311U

10/730,689

Independent claim 12 recites:

A method for treating a patient with angina, comprising:
providing a miniature implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator within the spinal column;
implanting the stimulator adjacent to at least one tissue influencing blood circulation, which tissue is at least one of the spinal roots;
providing operating power to the stimulator;
using an external appliance to transmit stimulation parameters to the stimulator;
receiving the stimulation parameters at the stimulator;
generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
delivering stimulation pulses via the stimulator to the at least one of the spinal roots influencing blood circulation as a treatment for said angina.

Applicant notes that claim 12 has been amended to recite a method for treating angina.

According to the Office Action, King teaches a method of treating angina that corresponds to claim 12. According to the Office Action, "King discloses a method for treating a patient with peripheral vascular disease (PVD) and angina (i.e. ischemia of the heart)." (Action of 6/22/06, p. 4).

While ischemia of the heart may be related to angina, the two are not synonymous. More importantly, King does not actually mention treating ischemia of the heart as implied by the Office Action. Rather, King actually teaches a method of treating "limb ischemia." (King, abstract; col. 2, lines 37-39; col. 5, lines 32-40). The title of King, "Apparatus and method for treating peripheral vascular disease and organ ischemia by electrical stimulation with closed loop feedback control," seems to imply that treating ischemia of the heart might be taught by the reference, no such teachings is actually included in the reference.

AB-311U

10/730,689

Consequently, the combination of cited prior art teachings as presented in the recent Office Action does not actually teach or suggest the claimed method of treating a patient with angina. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least these reasons, the rejection of claim 12 and its dependent claims should be reconsidered and withdrawn.

Claims 5, 6, 16 and 17 were rejected as unpatentable under 35 U.S.C. § 103(a) over the combination of King, Dooley and Schulman in further combination with Rise. This rejection is respectfully traversed for at least the same reasons given above regarding claims 1 and 12.

AB-311U

10/730,689

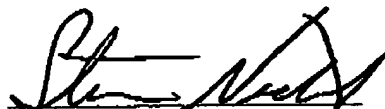
Conclusion:

The newly added claims are thought to be patentable over the prior art of record for at least the same reasons given above with respect to the original independent claims. Therefore, examination and allowance of the newly added claims is respectfully requested.

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper, that have not been authorized elsewhere, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: September 8, 2006

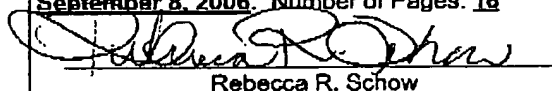


Steven L. Nichols
Registration No. 40,326

Steven L. Nichols, Esq.
Managing Partner, Utah Office
Rader Fishman & Grauer PLLC
River Park Corporate Center One
10653 S. River Front Parkway, Suite 150
South Jordan, Utah 84095
(801) 572-8066
(801) 572-7666 (fax)

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I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number **571-273-8300** on **September 8, 2006**. Number of Pages: **16**



Rebecca R. Schow